Session of 2006

HOUSE BILL No. 2820

By Committee on Appropriations

2-3

AN ACT concerning distribution of certain prescription drugs; enacting the wholesale licensure and prescription medication integrity act.

Be it enacted by the Legislature of the State of Kansas:

Section 1. Sections 1 through 8, and amendments thereto, shall be known and may be cited as the "wholesale licensure and prescription medication integrity act".

Sec. 2. As used in the wholesale licensure and prescription medication integrity act:

(a) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(b) "Chain pharmacy warehouse" means a physical location for drugs or devices, or both, that acts as a central warehouse and performs intracompany sales or transfers of the drugs or devices to a group of chain pharmacies that have the same common ownership and control.

(c) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

(d) "Normal distribution channel" means a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient.

(e) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug within the distribution channel.

(f) "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, or federal regulation, to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal food, drug and cosmetic act (FFDCA).

(g) "Repackage" means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dis-

pensing product to the patient.

(h) "Repackager" means a person who repackages.

(i) "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to, repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors; independent wholesale drug traders; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(j) "Wholesale distribution" shall not include:

(1) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity;

(2) the sale, purchase, distribution, trade or transfer of a prescription drug or offer to sell, purchase, distribute, trade or transfer a prescription drug for emergency medical reasons;

(3) the distribution of prescription drug samples by manufacturers' representatives;

(4) drug returns, when conducted by a hospital, health care entity or charitable institution in accordance with 21 C.F.R. § 203.23;

(5) the sale of minimal quantities of prescription drugs by a retail pharmacies to licensed practitioners for office use;

(6) retail pharmacies' delivery of prescription drugs to a patient or patient's agent pursuant to the lawful order of a licensed practitioner; or

(7) the sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(k) "Wholesaler" means a person engaged in the wholesale distribution of prescription drugs.

Sec. 3. (a) Each wholesale distributor who engages in the wholesale distribution of prescription drugs shall be licensed by the state board of pharmacy and every nonresident wholesale distributor shall be licensed in a state if it ships prescription drugs into that state, in accordance with this act before engaging in wholesale distributions of wholesale prescription drugs. The state board of pharmacy shall exempt manufacturers from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.

(b) The state board of pharmacy shall require the following minimum information from each wholesale distributor applying for a license under subsection (a) of this section:

(1) The name, full business address and telephone number of the licensee;

(2) all trade or business names used by the licensee;

(3) addresses, telephone numbers and the names of contact persons for all facilities used by the licensee for the storage, handling and distribution of prescription drugs;

(4) the type of ownership or operation, including, but not limited to, partnership, corporation or sole proprietorship;

(5) the name or names of the owner or operator of the licensee, including:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names and the state of incorporation; and

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(6) a list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;

(7) the name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to subparagraph (8) of subsection (b) of this section for such person; and

(8) each person required by subparagraph (7) of subsection (c) of this section to provide a personal information statement and fingerprints shall provide the following information to the state:

(A) The person's places of residence for the past seven years;

(B) the person's date and place of birth;

(C) the person's occupations, positions of employment and offices held during the past seven years;

(D) the principal business and address of any business, corporation or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(E) whether the person has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(F) whether, during the past seven years, the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control or distribution of prescription drugs or criminal violations, together with details concerning any such event;

(G) a description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed or stored pharmaceutical products and any lawsuits in which such businesses were named as a party;

(H) a description of any misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the state board of pharmacy a copy of the final written order of disposition; and

(I) a photograph of the person taken in the previous 30 days.

(c) The information required pursuant to subsection (b) of this section shall be provided under oath.

(d) The state shall not issue a wholesale distributor license of an applicant, unless the state:

(1) Conducts a physical inspection of the facility at the address provided by the applicant as required in subsection (b) of section 3 of this section; and

(2) determines that the designated representative meets the following qualifications:

(A) Is at least 21 years of age;

(B) has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of and recordkeeping relating to prescription drugs;

(C) has received a score of 75% or more on an examination given by the state board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs.

(D) is employed by the applicant full time in a managerial level position;

(E) is actively involved in and aware of the actual daily operation of the wholesale distributor;

(F) is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(G) is serving in the capacity of a designated representative for only one applicant at a time;

(H) does not have any convictions under any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(I) does not have any felony convictions under federal, state or local

laws.

(e) The state shall submit the fingerprints provided by a person with a license application for a statewide criminal record check and for forwarding to the federal bureau of investigation to conduct a national criminal record check of the person.

(f) The state board of pharmacy shall require every wholesale distributor applying for a license to submit a bond of at least $100,000, or other equivalent means of security acceptable to the state, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the state, pursuant to subsection (g) of this section. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding such license, which are authorized under state law and which the licensee fails to pay 30 days after the fines, penalties or costs become final. The state may make a claim against such bond or security until one year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state.

(g) There is hereby created in the state treasury the drug wholesaler trust fund. The executive secretary of the state board of pharmacy shall administer the fund. Proceeds from the bond prescribed by subsection (f) of this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance the state treasurer shall deposit the entire amount in the state treasury to the credit of the drug wholesaler trust fund. Moneys in the drug wholesaler trust fund may be expended for the purposes prescribed in subsection (f) of this section. All expenditures from the drug wholesaler trust fund shall be made in accordance with appropriation acts upon warrants of the director of accounts and reports issued pursuant to vouchers approved by the executive secretary of the state board of pharmacy.

(h) If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

(i) Every calendar year, the state board of pharmacy shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided pursuant to subsection (b) of this section. Within 30 days of receiving such form, the wholesale distributor must identify and state under oath to the state board of pharmacy all changes or corrections to the information that were provided pursuant to subsection (b) of this section. Changes in, or corrections to, any information in subsection (b) of this section shall be submitted to the state board of pharmacy as required by such board. The state board of pharmacy may suspend or revoke the license of a wholesale distributor

if such board determines that the wholesale distributor no longer qualifies for the license issued under this section.

(j) The designated representative identified pursuant to subsection (b)(7) of section 3 of this act must complete continuing education programs as required by the state board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs.

(k) Information provided under this section of this act shall not be disclosed to any person or entity other than a state board of pharmacy, government board or government agency provided such board or other state or federal agency needs such information for licensing or monitoring purposes.

Sec. 4. (a) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse, or both, including the returns of expired, damaged and recalled pharmaceutical product to either the original manufacturer or a third party returns processor, and such returns or exchanges shall not be subject to the pedigree requirement prescribed by section 5 of this act. Wholesale distributors shall be held accountable for policing their returns process and insuring that such returns are of products manufactured by their operations, are secure and do not permit the entry of adulterated and counterfeit product.

(b) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the state board of pharmacy. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the state board of pharmacy.

(c) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license, except that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) The identity and authorization of the recipient is properly established; and

(2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be

reported to the delivering manufacturer or wholesale distributor on or before the next business day after the delivery to the pharmacy receiving area.

(e) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner or owners of record, the chief executive officer or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

Sec. 5. (a) Each person who is engaged in the wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel.

(1) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(2) The state board of pharmacy shall conduct a study to be completed on or before January 1, 2007. Such report shall include consultation with manufacturers, distributors and pharmacies responsible for the sale and distribution of prescription drug products in the state. Based on the results of the study the state board of pharmacy shall determine a mandated implementation date for electronic pedigrees. The implementation date for the mandated electronic pedigree shall be no sooner than December 31, 2007.

(b) Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, who is in possession of a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree shall:

(1) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information shall include:

(A) Name, address, telephone number and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(B) the name and address of each location from which the product was shipped, if different from the owner's;

(C) transaction dates; and

(D) certification that each recipient has authenticated the pedigree.

(2) At minimum, the pedigree shall also include:

(A) Name of the prescription drug;

(B) dosage form and strength of the prescription drug;

(C) size of the container;

(D) number of containers;

(E) lot number of the prescription drug; and

(F) name of the manufacturer of the finished dosage form.

(d) Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and

(2) available for inspection or use within two business days upon a request of an authorized officer of the law.

(e) The state board of pharmacy shall adopt rules and a form relating to the requirements of this subsection no later than 120 days after the effective date of this act.

Sec. 6. (a) If the state finds that there is a reasonable probability that:

(1) A wholesale distributor, other than a manufacturer, has:

(A) Violated a provision in this act; or

(B) falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled or held a counterfeit prescription drug intended for human use.

(2) The prescription drug at issue as a result of a violation of paragraph (1) of subsection (a) of this section could cause serious, adverse health consequences or death; and

(3) other procedures would result in unreasonable delay, the state shall issue an order requiring the appropriate person, including the distributors or retailers of the drug to immediately cease distribution of the drug within that state.

(b) An order issued under subsection (a) of this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held no later than 10 days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the state determines that inadequate grounds exist to support the actions required by the order, the state shall vacate the order.

Sec. 7. It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(a) Failure to obtain a license in accordance with this act, or operating without a valid license when a license is required by this act;

(b) purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements prescribed by subsection (a) of section 3 of this act are met;

(c) the sale, distribution or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug, in violation of subsection (b) of section 4 of this act;

(d) failure to deliver prescription drugs to specified premises, as prescribed by subsection (c) of section 4 of this act;

(e) accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of section 4 of this act;

(f) failure to maintain or provide pedigrees as required by this act;

(g) failure to obtain, pass or authenticate a pedigree, as required by this act;

(h) providing the state or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this act;

(i) obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

(j) except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the United States food and drug administration, the manufacture, repacking, sale, transfer, delivery, holding or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution;

(k) except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the United States food and drug administration, the adulteration, misbranding or counterfeiting of any prescription drug;

(l) the receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit and the delivery or proffered delivery of such drug for pay or otherwise;

(m) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded; and

(n) such prohibited acts shall not include a prescription drug manufacturer or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the

prescription drug for authenticity.

Sec. 8. (a) A person convicted of violating section 7, and amendments thereto, shall be guilty of a drug severity level 1 felony.

(b) This section shall be part of and supplemental to the uniform controlled substances act.

Sec. 9. This act shall take effect and be in force from and after its publication in the statute book.